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Safety Evaluation of Nanoparticle Albumin-Bound Paclitaxel in Patients with Non-Small Cell Lung Cancer Based on CHPS: A Single Institution Retrospective Study

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ABSTRACT

Objective: To understand the incidence of adverse drug reactions (ADRs) caused by nanoparticle albumin-bound paclitaxel(nab-paclitaxel) in Non-Small Cell Lung Cancer (NSCLC) patients and to compare the reporting rate of China Hospital Pharmacovigilance System (CHPS) active monitoring with that of manual monitoring.

Methods: A retrospective analysis was conducted using the CHPS to establish an active monitoring protocol for nab-paclitaxel. The study subjects were lung cancer patients who used nab-paclitaxel at a hospital in China from September 1, 2022, to December 31, 2023. The study analyzed the incidence of ADRs related to the blood system, liver and kidney function, etc.

Results: A total of 89 cases were monitored, revealing ADRs such as leukopenia (24.72%), decreased hemoglobin (23.60%), neutropenia (21.35%), and alopecia (21.35%), all classified as grade 1-2. Other reactions included sensory neuropathy (16.85%), rash/pruritus (13.48%), nausea and vomiting (11.24%), and diarrhea (7.87%). The CHPS system exhibited significant advantages in detecting leukopenia, neutropenia, and decreased hemoglobin, with a sensitivity ranging from 90.91% to 95.24%, which far exceeds that of the manual group (27.27% to 38.10%). Furthermore, the specificity of most indicators was ≥ 97.01%.

Conclusion: In patients with NSCLCL, the most frequently observed ADRs linked to the off-label use of albumin-bound paclitaxel included hematological disorders such as anemia and leukopenia, along with alopecia. The implementation of the pharmacovigilance system for monitoring ADRs has led to an increased reporting rate, which merits further promotion.

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Introduction

Lung cancer is the second most common cancer worldwide and has the highest mortality rate. Non-small cell lung cancer (NSCLC) accounts for about 85% of all lung cancers, and about one-third of patients are already in the locally advanced stage (Stage III) at the time of diagnosis [1, 2].

Nanoparticle albumin-bound paclitaxel(nab-paclitaxel) is a microtubule inhibitor that avoids the adverse drug reactions (ADRs) brought by the polyoxyethylene castor oil (Cremophor CrEL) solvent system of traditional paclitaxel, including neurotoxicity and endothelial cell toxicity [3, 4]. Existing data have confirmed the role of nab-paclitaxel in the treatment of advanced NSCLC. Preliminary results from clinical studies Keynote-407 and IMpower131 indicate that the new combination of nab-paclitaxel/carboplatin and PD-1/PD-L1 inhibitors can further improve clinical benefits while keeping toxicity controllable [5]. In addition, the combination of nab-paclitaxel and radiotherapy is effective and well-tolerated in patients with locally advanced NSCLC [6, 7].

Although nab-paclitaxel has received approval from the U.S. FDA for the treatment of NSCLC, its application in China is regarded as off-label., and as its clinical application becomes more widespread, the issue of ADRs is also becoming more prominent. Previous reports showed that nab-paclitaxel can cause ADRs including nausea, vomiting, allergic reactions, bone marrow suppression, gastrointestinal reactions, etc [8, 9]. Especially after bone marrow suppression, patients are more likely to suffer from anemia, bleeding, and infections, further increasing the patient's physical burden, leading to chemotherapy delays and

interruptions, affecting treatment effects, and endangering life.

China Hospital Pharmacovigilance System (CHPS) is an information system used by the National Center for Adverse Drug Reaction Monitoring to discover, report, and evaluate adverse drug reactions, and to obtain pharmacovigilance information from key monitoring and post-marketing research [10]. By interfacing with and integrating internal hospital management systems, such as Hospital Information Systems (HIS), electronic medical records, and electronic medical order systems, authentic drug information is obtained. This process effectively identifies adverse drug reactions and verifies drug safety risks. Studies have shown that CHPS can effectively identify and manage ADRs such as anaphylactic shock, which is of great significance for improving patient safety and reducing ADRs [11].

This study conducted an automatic monitoring and case-control study on the medication population of patients with NSCLC in a top-tier hospital in China from September 1, 2022, to December 31, 2023, to obtain the incidence of ADRs and analyze them, providing a basis for the safe and rational use of nab-paclitaxel in patients with NSCLC.

1. Materials and Methods

1.1 Study Subjects and Content

From the Hospital Information System (HIS), we extracted in-patients with non-small cell chemotherapy who used nab-paclitaxel (trade name: KeRuiFei, Hunan Kelun Pharmaceutical Co, Ltd., specification: 100 mg/vial) from September 1, 2022, to December 31, 2023. The experimental group employed the China Pharmacovigilance System to develop an active surveillance model grounded in Boolean logic. The search criteria specified that during the target period, prescriptions for albumin-bound paclitaxel were issued to patients diagnosed with non-small cell lung cancer. In the process of retrieving these cases, instances of abnormalities in detection indicators or symptoms such as paresthesia, nausea, diarrhea, and alopecia were noted, with the onset occurring post-medication. This allowed the system to identify and filter positive cases effectively. In contrast, the control group was comprised of the manually reported statistical count of adverse drug reactions (ADRs) from the same cohort of inpatients during the specified period. Subsequently, two researchers independently reviewed the identified positive medical records within the target timeframe, adhering to the CTCAE v5.0 standards.

1.2 Inclusion and Exclusion Criteria and Alarm Trigger Rules

1.2.1 Inclusion Criteria: 1) Indication: Non-small cell lung cancer (NSCLC); 2) Age: >18 years; 3) Signed informed consent for off-label use of nab-paclitaxel.

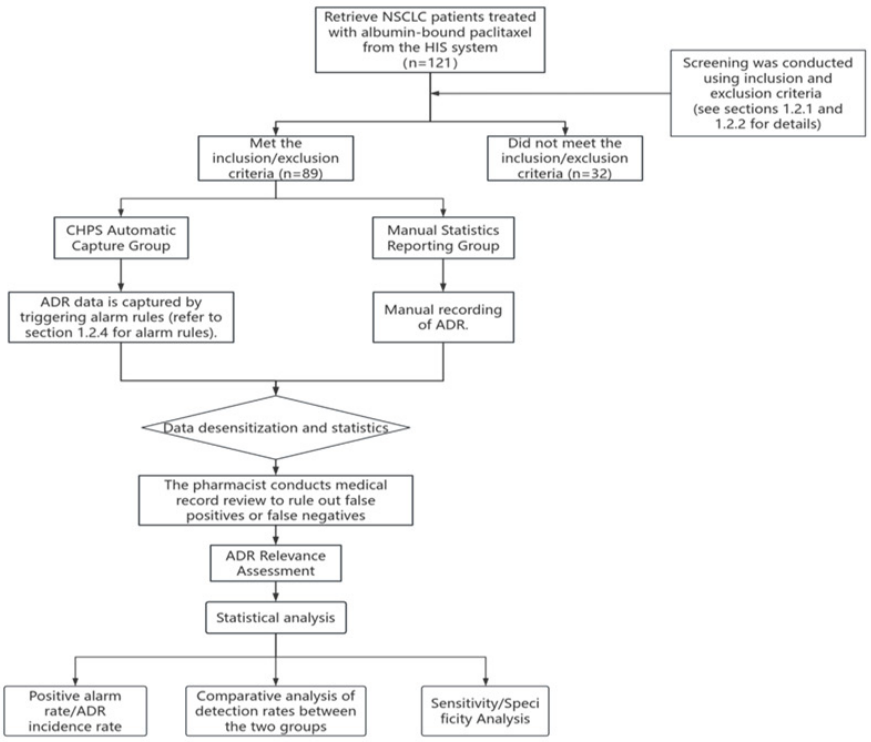
1.2.2 Exclusion criteria include: 1) Prohibited use of nab-paclitaxel as per the drug instructions; 2) Presence of abnormal baseline values before medication, which encompasses irregularities in the hematological system, liver function, kidney function, and other abnormal conditions noted in the medical history, such as those affecting the cardiovascular system, digestive system, and skin; 3) Missing test indicators.

1.2.3 Grouping: The analysis was conducted on the primary medical record data that met the inclusion and exclusion criteria. The experimental group comprised data generated from the automated capture of laboratory abnormalities (such as complete blood count, liver, and kidney function) and keywords from clinical course records (e.g., 'paresthesia', 'rash') of target patients through the China Hospital Pharmacovigilance System (CHPS), which generated adverse drug reaction (ADR) warning signals in real-time. The control group consisted of ADR cases identified and manually reported by clinicians following routine clinical procedures. Both groups captured ADR data from the same enrolled subjects. After conducting statistical analysis of the ADR data for both groups, the data were anonymized and subsequently aggregated.

1.2.4 CHPS System Alert Triggers and Manual Passive Reporting Statistical Rules: This section outlines the criteria for triggering alerts within the CHPS system. Specifically, it addresses abnormalities in test indicators or subjective discomfort experienced following the administration of medication. These criteria are essential for ensuring timely responses and appropriate interventions.:

White Blood Cell Count (WBC) < 3.5 x 10^9/L;
Platelet Count (PLT) < 125 × 10^9/L;
Hemoglobin (Hb):
Male < 130 g/L;
Female < 115 g/L;

Figure 1. Integrated study flowchart. The workflow includes data screening from HIS, grouping into CHPS-automated and manual reporting cohorts, alert triggering based on predefined thresholds, dual-pharmacist review to exclude false positives/negatives, and statistical analysis comparing ADR detection efficacy.



Liver Function Abnormalities:

Alanine Aminotransferase (ALT) > 1.5 × baseline value or increase > 17.5 U/L;

Aspartate Aminotransferase (AST) > 1.5 × baseline value or increase > 17.5 U/L;

Alanine Aminotransferase (ALT) > 1.5 × baseline value or increase > 22.5 U/L;

Total Bilirubin (TBIL) > 1.5 × baseline value or increase > 9.5 μmol/L;

Renal Function Abnormalities:

Serum Creatinine (Scr) > 1.5 × baseline value or > 40.5 μmol/L;

Urine Protein ≥ 1+;

Clinical Symptoms Documented in Medical Records: Arrhythmia, myocardial infarction, nausea, vomiting, diarrhea, myalgia/arthralgia, alopecia, rash, fever, allergic reactions, or other sensory system-related symptoms.

1.2.5 Medical Record Review: The initial medical records of both groups were meticulously reviewed by two clinical pharmacists to exclude any cases of false positives or false negatives. Finally, according to the association evaluation method in the "Drug Adverse Reaction Reporting and Monitoring Management Measures," cases with association evaluation results of "definite," "highly likely," or "possible" were determined as positive cases, ADRs were graded and assessed according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0 and were included in the final statistical analysis.

1.2.6 The screened data were summarized and organized using Microsoft Excel software, while data processing and analysis were conducted with SPSS version 27.0. The paired chi-square test was employed to analyze the ADR detection rates of various indicators between the CHPS automatic capture and manual reporting groups, and the McNamar test was utilized for this study, with a significance level set at $P < 0.05$. Finally, Excel was used to assess the sensitivity and specificity of the two groups.

The detailed inclusion and exclusion criteria, as well as the alarm-triggering rule process, are illustrated in Figure 1.

Table 1. Basic characteristics of patients included in nab-paclitaxel

Basic Features	Number of cases	Composition Ratio
Male	59	66.29%
Female	30	33.71%
Age (years)		
18~44	3	3.37%
45~59	22	24.72%
≥60	64	71.91%
Underlying Diseases		
None	61	68.54%
Hypertension	15	16.85%
Diabetes	4	4.49%
Hypertension with Diabetes	9	10.11%
Stage		
TNM stage I	0	0%
TNM stage II	12	13.48%
TNM stage III	29	32.59%
TNM stage IV	48	53.93%
Drug Combination		
1 drug (Albumin-bound paclitaxel)	12	13.48%
2 drugs (Albumin-bound paclitaxel + platinum-based drugs.)	45	50.56%
3 drugs(Albumin-bound paclitaxel + platinum-based drugs + immune checkpoint inhibitors)	32	35.96%

2. Results

2.1 Baseline Characteristics of Included Patients

From September 1, 2022, to December 31, 2023, a total of 121 NSCLC patients were hospitalized and administered nab-paclitaxel. Based on the exclusion criteria, 32 patients were omitted, leaving 89 patients for inclusion. Detailed data are presented in Table 1. The findings indicate that patients experiencing a higher incidence of ADRs are predominantly male, aged 60 or older, with advanced NSCLC (stage IV), and taking two or more drugs concurrently. The influence of underlying diseases on the occurrence of ADRs appears to be insignificant.

2.2 Comparison between the CHPS Active Monitoring Group and the Manual Passive Reporting Group.

A total of 89 patients who met the inclusion and exclusion criteria were analyzed for adverse drug reaction (ADR) data collected through both automated reporting by the China Hospital Pharmacovigilance System (CHPS) and manual passive reporting. The data were meticulously reviewed by clinical pharmacists before analysis. The results indicated that the identification rate of the CHPS was significantly higher than that of manual reporting across multiple indicators ($p < 0.05$). Specifically, CHPS exhibited notably superior positive detection rates compared to manual reporting for leukopenia (24.72% *vs* 6.74%, $p < 0.001$), neutropenia (20.22% *vs* 6.74%, $p < 0.001$), decreased hemoglobin (23.60% *vs* 8.99%, $p < 0.001$), sensory neuropathy (14.61% *vs* 5.62%, $p = 0.008$), rash/pruritus (12.36% *vs* 5.62%, $p = 0.031$), and alopecia (17.98% *vs* 11.24%, $p = 0.031$). No statistically significant differences were observed between the two groups regarding thrombocytopenia, elevated transaminase levels, elevated bilirubin levels, elevated creatinine levels, diarrhea, nausea/vomiting, and headache/dizziness ($p > 0.05$).

Further analysis indicated that the CHPS group exhibited particularly remarkable performance in sensitivity, as detailed in Table 3. For example, its detection efficacy for leukopenia (90.91% *vs*. 27.27%), neutropenia (94.74% *vs*. 31.58%), and decreased hemoglobin (95.24% *vs*. 38.10%) was significantly superior to that of the manual reporting group. Furthermore, CHPS maintained a high level of specificity, with most indicators demonstrating specificity values

Table 2. Results of ADRs Captured by CHPS Automatic Reporting and Manual Reporting for nab-paclitaxel

Monitoring Items	Manual review of ADR cases	The CHPS system automatically reports the number of ADR cases	Positive alarm rate (%) of the CHPS system	Manually reported ADR cases	Manual reporting positive alarm rate (%)	p-value
Leukopenia	22	20	22.47%	6	6.74%	<0.001
Neutropenia	19	18	20.22%	6	6.74%	<0.001
Thrombocytopenia	7	7	7.87%	7	7.87%	1
Anemia	21	20	22.47%	8	8.99%	<0.001
elevated transaminase levels	10	9	10.11%	7	7.87%	0.375
Elevated bilirubin levels	4	4	4.49%	2	2.25%	0.5
Kidney Function Damage	2	2	2.25%	2	2.25%	1
Diarrhea	7	5	5.62%	5	5.62%	1
Nausea, vomiting	10	8	8.99%	4	4.49%	0.125
headache, dizziness	4	3	3.37%	2	2.25%	1
sensory neuropathy	15	13	14.61%	5	5.62%	0.008
rash, pruritus	12	11	12.36%	5	5.62%	0.031
alopecia	19	16	7.98%	10	11.24%	0.031

Table 3. Comparison of sensitivity and specificity in capturing ADRs detection results between the CHPS group and the manual passive reporting group

Monitoring Items	CHPS group		Manual Reporting Group	
	Sensitivity	Specificity	Sensitivity	Specificity
Leukopenia	90.91%	97.01%	27.27%	100.00%
Neutropenia	94.74%	100.00%	31.58%	100.00%
Thrombocytopenia	100.00%	100.00%	85.71%	97.56%
Anemia	95.24%	98.53%	38. 10%	98.53%
elevated transaminase levels	90.00%	97.47%	80.00%	98.73%
Elevated bilirubin levels	100.00%	100.00%	50.00%	100.00%
Kidney Function Damage	100.00%	100.00%	100.00%	100.00%
Diarrhea	71.43%	100.00%	71.43%	100.00%
Nausea, vomiting	80.00%	100.00%	40.00%	100.00%
headache, dizziness	75.00%	100.00%	50.00%	100.00%
sensory neuropathy	86.67%	100.00%	33.33%	100.00%
rash, pruritus	91.67%	100.00%	41.67%	100.00%
alopecia	84.21%	100.00%	52.63%	100.00%

Note:Collect and compare the Adverse Drug Reaction (ADR) data from the CHPS group and the manually passive reporting system with the data obtained from manually reviewed ADRs, and subsequently calculate the sensitivity and specificity.

Table 4. Adverse Drug Reactions (ADRs) by Organ System and CTCAE Grade (Grade 3/4 Proportion)

System/Organ	Trigger	Number of Cases by CTCAE Grade				Proportion of Total ADRs (%)	Grade 3/4 (%)
		Grade 1	Grade 2	Grade 3	Grade 4		
Blood System	Leukopenia	10	6	4	2	24.72%	6.74%
	Neutropenia	8	5	3	3	21.35%	6.74%
	Thrombocytopenia	4	2	1	/	7.87%	1.12%
	Anemia	11	7	3	/	23.60%	3.37%
Liver System	elevated transaminase levels	5	4	1	/	11.24%	1.12%
	Elevated bilirubin levels	3	1	/	/	4.49%	0.00%
Kidney and Urinary System	Kidney Function Damage	1	1	/	/	2.25%	0.00%
Gastrointestinal System	Diarrhea	5	2	/	/	7.87%	0.00%
	Nausea, vomiting	6	3	1	/	11.24%	1.12%
Nervous System	headache, dizziness	3	1	/	/	4.49%	0.00%
	sensory neuropathy	10	4	1	/	16.85%	1.12%
Skin and Appendages	rash, pruritus	8	4	/	/	13.48%	0.00%
	alopecia	12	7	/	/	21.35%	0.00%

Note:ADR grading is based on the CTCAE v5.0 standard. It is important to note that the symbol '/' indicates the absence of available case reports for this grade. Furthermore,the ADR data in the table are derived from manual review of case materials, and the proportion calculation is based on the total number of ADR cases (N=89).

≥ 97.01%. Notably, it achieved 100% specificity in indicators such as thrombocytopenia, elevated bilirubin, and increased creatinine. It is important to highlight that although the manual reporting group exhibited specificity comparable to that of the CHPS group in certain indicators (such as elevated transaminase) (98.73% vs. 97.47%), its sensitivity was lower than that of the CHPS group (80.00% vs. 90.00%).

In summary, the CHPS system has been shown to significantly improve the early identification of adverse drug reactions (ADRs) through automated data integration and the establishment of multi-dimensional thresholds. It demonstrates high efficiency and reliability, particularly in detecting related ADRs in both the blood and nervous systems.

2.3 Incidence of ADRs associated with nab-paclitaxel and the involved organs and systems.

A statistical analysis was conducted on the 89 patients who experienced adverse drug reactions (ADRs). The involved organ systems and severity levels of these reactions were categorized and summarized. The detailed results are presented in Table 4.

Studies have demonstrated that the ADRs associated with NTP in the treatment of non-small cell lung cancer predominantly affect the hematopoietic system. These reactions are primarily characterized by leukopenia (24.72%), neutropenia (21.35%), decreased hemoglobin (23.60%), and thrombocytopenia (7.87%), which together account for 45.40% of all reported ADRs. Notably, the most severe grade 3/4 ADRs are primarily leukopenia (6.74%), neutropenia (6.74%), and decreased hemoglobin (3.37%). This highlights the necessity for focused attention on the risk of bone marrow suppression.

The characteristics of other ADRs include the highest incidence of alopecia in skin and appendages at 21.35%, all of which were classified as grade 1-2. The incidence of rash or pruritus was 13.48%. Gastrointestinal ADRs, such as nausea and vomiting,

occurred in 11.24% of cases, while diarrhea was reported in 7.87%. Notably, there was only one grade 3 event of nausea and vomiting, accounting for 1.12%. The incidence of sensory neuropathy in the nervous system was 16.85%, which is significantly higher than the incidences of headache and dizziness at 4.49%. Regarding liver and kidney function impairment, the increases in transaminase (11.24%), bilirubin (4.49%), and creatinine (2.25%) were predominantly mild, with no grade 3 or 4 events observed.

It is noteworthy that there were 19 instances of grade 3/4 severe ADRs, accounting for 12.50% of the total ADRs, which were primarily concentrated in the hematopoietic system, including bone marrow suppression, leukopenia, and anemia. This necessitates enhanced monitoring and management during clinical medication. No fatal severe ADRs were reported in this study.

3. Discussion

In this study, we investigated the safety characteristics of nab-paclitaxel in NSCLC through active monitoring of CHPS. Given that nab-paclitaxel exhibits significant anti-tumor activity and is classified as a cytotoxic drug, the overall incidence of ADRs is notably high. Furthermore, the incidence of ADRs within the hematological system is relatively elevated, followed by gastrointestinal reactions and neurotoxicity. These findings are consistent with previously reported data. It was noted that patients with lung cancer treated with nab-paclitaxel experienced significant ADRs, primarily anemia and gastrointestinal issues [12]. Additionally, the most common hematological grade 3 or higher treatment-related adverse events associated with nab-paclitaxel included neutropenia (30.8%), leukopenia (23.1%), and anemia (1.5%) [13].

This study employed active monitoring methods to compare data with manually reported ADRs. The findings indicate that the incidence rate of ADRs detected through the CHPS monitoring system is significantly higher than that reported through manual methods. The study found that the CHPS system exhibited significant advantages in detecting leukopenia, neutropenia, and decreased hemoglobin, with a sensitivity range of 90.91% to 95.24%, which far exceeds that of the manual group, recorded at 27.27% to 38.10%. The specificity for most indicators was ≥ 97.01%, with the specificity for thrombocytopenia, bilirubin elevation, and creatinine elevation reaching 100%. Although the manual group demonstrated specificity comparable to that of CHPS for certain hepatotoxicity indicators (98.73% vs. 97.47%), its sensitivity was notably inadequate (80.00% vs. 90.00%). Furthermore, existing literature corroborates that the ADR data monitored by CHPS exceeds the reported rate of ADRs observed manually in clinical studies [14,15].

Among the observed ADRs, anemia and leukopenia were the most prevalent. The incidence of ADRs included decreased white blood cell count, decreased hemoglobin levels, neutropenia, alopecia, sensory neuropathy, pruritic rash, elevated liver enzymes, nausea and vomiting, diarrhea, and thrombocytopenia. Notably, these findings exhibited certain discrepancies when compared to other studies. Research findings vary. According to a previous report [12], the side effects of nab-paclitaxel, whether used alone or in combination with immune checkpoint inhibitors in patients with small cell lung cancer, predominantly involve bone marrow suppression reactions such as leukopenia and neutropenia. These are followed by ADRs including nausea, vomiting, and liver toxicity, while the incidence of anemia-related ADRs is relatively low. Similarly, it has been reported that common ADRs in patients with platinum-resistant urothelial cancer treated with nab-paclitaxel included peripheral neuritis, fatigue, alopecia, nausea, loss of appetite, and constipation [13].

Anemia, recognized as the most prevalent adverse reaction in patients with non-small cell lung cancer (NSCLC) undergoing treatment with nab-paclitaxel, may exhibit a higher incidence rate due to an increased proportion of drug combinations and extended treatment cycles. A meta-analysis indicates that nab-paclitaxel is more likely to induce grade 3/4 anemia, thrombocytopenia, and neurotoxicity compared to conventional Taxane [12]. Our study suggests a correlation between the drug combination regimens and treatment cycles of nab-paclitaxel may be associated with the occurrence of anemia ADRs. These findings underscore the critical need for monitoring hematological abnormalities within drug management plans, particularly for patients requiring prolonged treatment. Consequently, we recommend that healthcare providers closely monitor essential laboratory indicators, such as complete blood counts and liver and kidney function tests, including these as routine examination items to ensure the safety and efficacy of patient medication. Additionally, greater attention should be directed towards elderly patients, those receiving multiple concurrent

anti-tumor agents, and those undergoing extended treatment regimens.

Interestingly, the incidence of peripheral neurotoxicity in this study was found to be lower than that reported in a meta-analysis of 24 trials [18], which indicated a higher incidence of peripheral neuropathy associated with nab-paclitaxel. This discrepancy may be attributed to the cumulative dose of the drug. Furthermore, deeper underlying factors such as the ABCC2-24C/T gene polymorphism or increased drug uptake by nerve cells, could also play a role [19,20]. Nevertheless, the relatively low incidence of peripheral neurotoxicity observed in this study may be linked to the administration of methyl cobalamin and other preventive medications during treatment. Previous research has shown that drugs such as methyl cobalamin and glutathione can significantly reduce the incidence and severity of chemotherapy-induced peripheral neuropathy in patients with multiple myeloma [21].

In our study, the hospital pharmaceutical management committee approved the use of nab-paclitaxel for patients with non-small cell lung cancer (NSCLC) based on multiple evidence-based guidelines [22], FDA-approved indications, and dynamic adverse drug reaction (ADR) data from our hospital's monitoring system. The CHPS system has continuously monitored ADRs associated with off-label use of nab-paclitaxel for over one year and three months, during which no serious ADRs resulting in death were observed. Overall, the risks associated with nab-paclitaxel in NSCLC patients are considered acceptable, manageable, and predictable.

As a sentinel monitoring system, the CHPS has demonstrated strong performance in evaluating drug safety and is highly recommended for broader implementation [23]. In this study, we propose a safety assessment method for anti-tumor drugs based on the CHPS system. The primary advantage of this research lies in the active monitoring role that CHPS plays in evaluating the safety of anti-tumor drug usage. Compared to passive monitoring, this method achieves a higher detection rate of ADRs. Furthermore, it demonstrates greater sensitivity and specificity for certain indicators, facilitating a systematic understanding of the actual risks associated with ADRs. Currently, there is no globally unified model for the active monitoring of chemotherapy drug ADRs making our study a valuable contribution to the field [24,25]. Furthermore, as the CHPS system utilizes information from electronic medical records, our data source is highly reliable.

However, this study has several limitations. First, as a single-center retrospective study, it is prone to selection bias, and data regarding mild symptoms may be overlooked, potentially leading to inaccurate recording of ADR incidence. Second, the single-center design may restrict the generalizability of our findings to the broader population. Furthermore, in our hospital's clinical practice, nab-paclitaxel is primarily utilized in combination therapy, with a smaller proportion of patients receiving it as monotherapy. This discrepancy may introduce bias in the monitoring of adverse drug reactions. Therefore, future large-scale, multicenter, prospective cohort studies are necessary to validate these results in a more diverse population.

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Conflict of interest: None

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